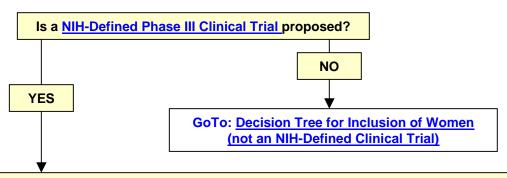
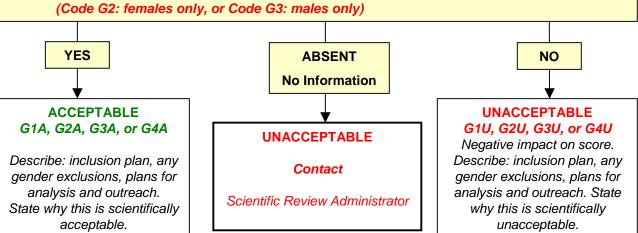


Decision Tree for Inclusion of Women in NIH-Defined Phase III Clinical Trials



Is gender representation acceptable?

- Strong evidence exists for significant gender differences in intervention effect and study design or analysis can answer primary question(s) separately for each gender and the analysis plan can detect significant differences in intervention effect? (Code G1: both genders included) or
- 2. Strong evidence exists for NO significant gender differences in intervention effect?
 - (Code G1: both genders included, or Code G2: females only, or Code G3: males only) or
- 3. No clear evidence exists for or against significant gender differences in intervention effect and study design and analysis plans will permit <u>valid analysis</u> of a differential intervention effect? (Code G1: both genders included) or
- 4. One gender is excluded because inclusion is inappropriate with respect to their health or because the research question is relevant to only one gender?



Summary of Codes Representation is Scientifically... **Gender Representation** Acceptable Unacceptable Both genders included G1A G₁U Females only G2A G2U Males only G3A G3U Unknown (cannot be known) G4A G4U